

Remarks

In the outstanding Official Action, the Examiner:

(1) objected to the drawings and stated that Figs. 2-7 should be designated by a legend such as -- Prior Art -- because only that which is old is illustrated;

(2) objected to the disclosure because the specification does not include a brief description of the drawings, required appropriate correction, and suggested that Applicant insert headings in the specification;

(3) rejected claim 2 under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention; and

(4) rejected claims 1 and 2 under 35 USC 102(e) as being anticipated by Harwin.

In response to Item 1 above, Applicant has now amended Figs. 2-7 to include the legend -- Prior Art --. A proposed drawing correction for Figs. 2-7 is submitted herewith. Accordingly, Applicant believes that Figs. 2-7 should be acceptable since they have been corrected as suggested by the Examiner.

In response to Item 2 above, Applicant has now amended the specification so as to insert a brief description of the drawings and also to insert headings in the specification. No new matter has been

introduced by these amendments to the specification. In addition, the specification has been amended to discuss the round shim bearing surfaces shown and explicitly annotated on Figs. 11 and 11A. Again, no new matter has been introduced by these amendments to the specification. Accordingly, Applicant believes that the specification should be acceptable as amended above.

In response to Item 3 above, Applicant has now amended claim 2 so as to more particularly point out and distinctly claim the subject matter of the present invention. Specifically, claim 2, at line 10, has now been amended so as to delete "said" and insert --a-- in place thereof. Accordingly, Applicants believe that claim 2 is now in condition for allowance.

In response to Item 4 above, Applicant has now canceled claim 1 and added new claims 3-13. Applicant respectfully traverses the rejection under 35 USC 102(e) with respect to claim 2.

Claim 2 of the present invention comprises the step of attaching the at least one ligament to the bone prior to the step of inserting the ligament shim into the bone tunnel so as to occupy a portion of the transverse cross-sectional area of the bone tunnel. Applicant believes that Harwin discloses a method of fixation of a graft in a bone comprising wedging the shim wedge member into the space formed between a graft and a bone tunnel wall to an extent sufficient to fixedly secure the graft against the bone and prevent

loosening. With Harwin, the shim wedge member is the only fastener used to secure the ligament to the bone; with Applicant's invention, another fastener secures the ligament to the bone, and the ligament shim helps close off the bone tunnel, provide a bearing surface, etc. Therefore, Harwin is believed to teach away from the present invention. Accordingly, claim 2 is believed to be in condition for allowance, and allowance thereof is respectfully requested.

New claim 3 calls for a shim comprising a rounded bearing surface being formed at the first end of the body, the first end being positionable at a proximal end of the bone tunnel, adjacent the mouth and the at least one ligament, so as to position the rounded bearing surface to provide a gentle bearing surface for the at least one ligament. Applicant believes that the rounded bearing surface of the shim is not taught or suggested by the prior art. Accordingly, new claim 3 is believed to be in condition for allowance, and allowance thereof is respectfully requested.

New claims 4 and 5 call for a shim comprising a body forming a tow hole therethrough between the first end and the second end thereof, the tow hole extending substantially orthogonal to the longitudinal axis, wherein the shim is positionable within the bone tunnel by pulling a suture inserted through the tow hole. Applicant believes that the prior art does not teach or suggest the present invention comprising a shim with a tow hole extending substantially orthogonal to the

longitudinal axis, wherein the shim is positionable within the bone tunnel by pulling a suture inserted through the tow hole. Accordingly, new claims 4 and 5 are believed to be allowable, and allowance thereof is respectfully requested.

New claims 6 and 7 call for a shim comprising a first pair of opposing arcuate surfaces being formed by the a least two walls, the first pair of opposing arcuate surfaces curving inwardly toward one another and being formed substantially along the longitudinal axis from the first end to the second end. Applicant believes that this shim construction with a pair of opposing arcuate surfaces is not taught or suggested by the prior art. Accordingly, new claims 6 and 7 are believed to be in condition for allowance, and allowance thereof is respectfully requested.

New claim 8 calls for first and second pairs of opposing arcuate surfaces being formed by the at least two walls, each of the first and second pairs of opposing arcuate surfaces curving inwardly toward one another, respectively, and each of the first and second pairs of opposing arcuate surfaces being formed substantially along the longitudinal axis from the first end to the second end. Applicant believes that this shim construction with first and second pairs of opposing arcuate surfaces is not taught or suggested by the prior art. Accordingly, new claim 8 is believed to be in condition for allowance, and allowance thereof is respectfully requested.

New claim 9 calls for positioning a shim in the interstitial space of a new bone tunnel between at least one ligament and an old bone tunnel so as to close off the new bone tunnel from the old bone tunnel, and so as to keep the at least one ligament from falling into the old bone tunnel. Applicant believes that the prior art does not teach or suggest a method comprising positioning the shim in the interstitial space of a new bone tunnel between at least one ligament and the old bone tunnel. Accordingly, new claim 9 is believed to be in condition for allowance, and allowance thereof is respectfully requested.

New claims 10-13 call for a system comprising suspension means for suspending at least one ligament within the bone tunnel, and a shim being separate from the suspension means and configured to gently urge the at least one ligament toward a wall of the bone tunnel. Applicant believes that the prior art does not teach or suggest a system comprising suspension means and a shim being separate from the suspension means. Accordingly, new claims 3-13 are believed to be in condition for allowance, and allowance thereof is respectfully requested.

On account of the foregoing, claims 2-13 are believed to be in condition for allowance. Early and favorable reconsideration is therefore respectfully requested.

In event that any additional fees may be required
in this matter, please charge the same to Deposit
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Respectfully submitted,

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Version With Markings To Show Changes Made

IN THE SPECIFICATION:

LIGAMENT SHIM

Background Of The Invention

This patent application claims benefit of pending prior U.S. Provisional Patent Application Serial No. 60/143,241, filed 07/09/99 by Joseph H. Sklar for LIGAMENT SHIM, which patent application is incorporated herein by reference.

A ligament is a piece of fibrous tissue which connects one bone to another.

Ligaments are frequently damaged (e.g., detached or torn or ruptured, etc.) as the result of injury and/or accident. A damaged ligament can impede proper motion of a joint and cause pain.

Various procedures have been developed to repair or replace a damaged ligament. The specific procedures used depend on the particular ligament which is to be restored and the extent of the damage.

One ligament which is frequently damaged as the result of injury and/or accident is the anterior cruciate ligament (ACL). The ACL 2 extends between the top of the tibia 4 and the bottom of the femur 6 (Fig. 1). A damaged ACL can cause instability of the knee joint and cause substantial pain and arthritis.

Numerous procedures have been developed to restore the ACL through a graft ligament replacement. In general, these ACL 2 replacement procedures (Fig. 2) involve drilling a bone tunnel 8 through the tibia 4 and up into the femur 6. Then a graft ligament 10, consisting of a harvested or artificial ligament or tendon(s), is passed through the tibial tunnel 12, across the interior of the joint, and up into the femoral tunnel 14. Then a distal portion of the graft ligament is secured in the femoral tunnel 14 and a proximal portion of the graft ligament is secured in the tibial tunnel 12.

There are currently several different ways to secure a graft portion in a bone tunnel. One way is to use an interference screw 16 (Fig. 2) to aggressively wedge the graft ligament against the side wall of the

bone tunnel. Another way is to suspend the graft ligament in the bone tunnel with a suture 18 (Fig. 3) or a cross-pin 20 (Fig. 4). Still another way is to pass the graft ligament completely through the bone tunnel and affix the ligament to the outside of the bone with a screw and washer arrangement 22 (Fig. 2) or a staple (not shown).

Depending on the fixation device and its manner of use, some fixation will occur at the portion of the bone tunnel nearest to the interior of the joint, and some fixation will occur intermediate the bone tunnel or adjacent to the portion of the bone tunnel farthest from the interior of the joint. For example, an interference screw 16 set into the femur 6 will typically be positioned substantially adjacent to the interior of the joint 26 (Fig. 5); however, an interference screw 16 set into the tibia 4 will frequently be positioned relatively far from the interior of the joint 26 (Fig. 6). On the other hand, suture 18 (Fig. 3) and cross-pin 20 (Fig. 4) suspensions will typically effect securing intermediate the length of the bone tunnel or at the far end of the

bone tunnel, and screw and washer fixations 22 (Fig. 2) will typically effect securing relatively far from the interior of the joint 26.

It has been observed that whenever the graft ligament is secured remote from the interior of the joint 26 (i.e., in the middle of the bone tunnel or adjacent to an outer surface of the bone), the graft ligament 10 will be relatively unsupported at the point where the ligament 10 passes from the bone tunnel into the interior of the joint. As a result, as the knee flexes back and forth through its natural range of motion (Fig. 7), the graft ligament moves about within the mouth 28 of the bone tunnel, rubbing against the walls of the bone tunnel. Over time, this can cause damage to the graft ligament and the wear down the mouth 28 of the bone tunnel, both to the serious detriment of the patient. It can also result in enlargement of the entire tunnel diameter, e.g., as [show] shown at 30. Less than a tight fit may result in incursion of synovial fluid into the tunnel, which is hypothesized to contribute to the tunnel-widening phenomenon.

Brief Description Of The Drawings

Fig. 1 is a schematic illustration of an ACL extending between the top of the tibia and the bottom of the femur;

Fig. 2 is a schematic illustration of an ACL replacement procedure using an interference screw to wedge a graft ligament against the side wall of a bone tunnel;

Fig. 3 is a schematic illustration of an ACL replacement procedure using a suture to suspend a graft ligament in a bone tunnel;

Fig. 4 is a schematic illustration of an ACL replacement procedure using a cross-pin to suspend a graft ligament in a bone tunnel;

Fig. 5 is a schematic illustration of an interference screw set into a femur and positioned substantially adjacent to the interior of the joint;

Fig. 6 is a schematic illustration of an interference screw set into a tibia and positioned relatively far from the interior of the joint;

Fig. 7 is a schematic illustration of a graft ligament within the mouth of a bone tunnel, the bone

tunnel having an enlarged bone tunnel diameter from the graft ligament moving about within the mouth of the bone tunnel;

Fig. 8 is a schematic illustration of a shim provided for insertion into the mouth of a bone tunnel;

Fig. 9 is a schematic illustration of a peripheral shim adapted to fit between a graft ligament and the wall of a bone tunnel;

Fig. 10 is a schematic illustration of the peripheral shim suspended by a suture inserted through a shim hole therein;

Fig. 11 is a schematic illustration of a shim having an outer surface in the shape of an arc so as to conform to a round bone tunnel wall;

Fig. 11A is a schematic illustration of a shim having both an outer surface and an inner surface in the shape of an arc so as to conform to both the round bone tunnel wall and the round graft ligament;

Fig. 12 is a schematic illustration of a centerline shim adapted to fit between two graft ligament strands;

Fig. 13 is a schematic illustration of the peripheral shim suspended by a suture inserted through a shim hole therein;

Fig. 14 is a schematic illustration of a centerline shim having two opposing surfaces in the shape of an arc so as to conform to two round graft ligament strands;

Fig. 15 is a schematic illustration of a centerline shim having a first set of two opposed surfaces in the shape of an arc and a second set of two opposed surfaces in the shape of an arc so as to conform to four round graft ligament strands;

Fig. 16 is a schematic illustration of exemplary implementations of the centerline shim;

Fig. 17 is a schematic illustration of a new bone tunnel placed close to an old bone tunnel so as to overlap one another, so as to allow a graft ligament strand to fall into the old bone tunnel hole; and

Fig. 18 is a schematic illustration of a peripheral shim used to close off the new bone tunnel hole from the old bone tunnel hole, so as to keep the

graft ligament from falling into the old bone tunnel hole.

Detailed Description Of The Preferred Embodiments

The solution to this problem is to provide a shim 32 for insertion into the mouth 28 of the bone tunnel (Fig. 8). The shim 32 is formed and sized so as to take up additional space present at the mouth 28 of the bone tunnel and, at the same time, to urge the ligament against the opposing side walls of the bone tunnel. By taking up additional space at the mouth of the bone tunnel, the aforementioned windshield wiper effect can be effectively eliminated. In addition, the entrance to the bone tunnel will be better sealed against migration of synovial fluid out of the joint and into the bone tunnel. This can be important, since incursion of synovial fluid into the bone tunnel is believed to be deleterious to the ligament reconstruction and to contribute to tunnel widening. At the same time, by urging the graft ligament 10 against the opposing side walls of the bone tunnel 8,

osseo-integration between the graft ligament and the host bone will be enhanced. If desired, the shim 32 can be sized and positioned so as to force the ligament 10 against the opposing side walls of the bone tunnel 8 with substantial force so as to enhance attachment of the graft ligament 10 to the bone. However, it should also be appreciated that it is not necessary for the ligament shim 32 to force the ligament against the opposing side walls of the bone tunnel with any great force, since the primary purpose of the shim is simply to occupy excess bone tunnel space, not to compressively secure the ligament to the bone. In other words, the primary purpose of the ligament shim is to form a strategically-placed extension of the bone tunnel wall, rather than to replace an interference screw.

The ligament shim can take the form of two basic embodiments; a peripheral shim 34 and a centerline shim 36.

The peripheral shim 34 is adapted to fit between the graft ligament 10 and a wall of the bone tunnel (Fig. 9). Thus, the shim effectively provides an

extension of the bone wall which it lies against, so as to eliminate the windshield wiper effect discussed above. In one form of the invention, the shim 34 is intended to be held in place through a simple friction fit between the wall of the bone tunnel and the graft ligament. If desired, the shim can be tapered (Figs. 8 and 9) so as to give it a wedge-like configuration and/or the surfaces of the shim can be configured with ribs and/or roughening so as to increase friction with the adjacent anatomy. In another form of the invention, the shim can be suspended by a suture 38 which passes through a shim hole 39 (Fig. 10). Preferably, a shim has at least its outer surface in the shape of an arc (Fig. 11), so that it can conform to the round bone tunnel wall. In one embodiment, the shim has both its inner and outer surfaces in the shape of an arc 42 (Fig. 11A), so that it can conform to both the round bone tunnel wall and the round graft ligament. If desired, more than one shim can be applied about the periphery of the mouth of the bone tunnel. Alternatively, a single shim can be

constructed so that it covers a significant portion of the periphery of the bone tunnel wall.

Still looking at Figs. 11 and 11A, and in a preferred embodiment of the present invention, there is shown peripheral shim 34 having round surfaces at the proximal end thereof. Peripheral shim 34 may be disposed within a bone tunnel such that these round surfaces provide gentle bearing surfaces for the ligament near the mouth of the bone tunnel.

In some circumstances, the graft ligament consists of single strand of tissue (Fig. 9). In other circumstances, the graft ligament consists of two or more strands 44 of tissue which extend parallel to one another so as to collectively form the graft ligament 10 (Fig. 12). For example, suture and cross-pin suspensions are typically created by looping a long hamstring graft 44 over a suture loop or cross-pin; in this case, there are two graft ligament strands extending parallel to one another in the bone tunnel. The centerline shim 36 is adapted to fit between two such graft ligament strands 44. The centerline shim 36 can be maintained in place through a

simple friction fit between the two ligament strands 44 (Fig. 12). Again, the shim can be tapered along its length so as to give it a wedge-like configuration, and/or the surfaces of the shim can be configured with ribs and/or roughening so as to increase friction with adjacent anatomy. Alternatively, the shim can be suspended by a suture 38 passing through a shim hole 39 (Fig. 13). Preferably, the centerline shim has its two opposing surfaces in the shape of an arc 46, so that the shim can conform to the two round graft ligament strands (Fig. 14). This construction will help keep the centerline shim 36 seated between the ligament strands 44. In some cases, more than two ligament strands 44 might be used in the ligament reconstruction. For example, four ligament strands might be used in the reconstruction. In this case, the shim might comprise four arced surfaces 48 (Fig. 15). Numerous implementations of the centerline shim 36 are contemplated (Fig. 16).

Both the peripheral shim and the centerline shim also provide a benefit beyond simply curing the aforementioned windshield wiper effect. More

specifically, at the same time that the shims take up excess room within the bone tunnel, they also urge the graft ligament into engagement with the walls of the bone tunnel. This urging facilitates osseo-integration between the graft ligament and the host bone, thereby improving surgical results.

In some cases, it may be necessary to redo, or "revise", an earlier ACL reconstruction. This frequently involves forming a new bone tunnel hole adjacent to the old bone tunnel hole. If the old bone tunnel hole 50 occupied a less than ideal position in the host bone 52, it is generally desirable to place the new bone tunnel hole 54 in a better position than the old bone tunnel hole. In some circumstances, the new bone tunnel hole will be placed so close to the old bone tunnel 50 hole that the two will actually overlap (Fig. 17). In this case, there may be a danger of a graft ligament strand 10 "falling" out of the new bone tunnel hole and into the old bone tunnel hole, e.g., as show at 56. With the present invention, a peripheral shim 34 may be used (Fig. 18) so as to close off the new bone tunnel hole 54 from the old bone tunnel hole

50, so as to keep the graft ligament strand from falling into the old bone tunnel hole 50.

It should be appreciated that while the present invention has been discussed above in the context of an ACL reconstruction, it is not intended to be limited to just ACL reconstructions. The present invention will also find application in other sorts of reconstructions, e.g., other types of ligament reconstructions, etc.

IN THE CLAIMS:

2. (Amended) A method for securing at least one ligament to a bone within a bone tunnel, the bone tunnel having a transverse cross-sectional area greater than a transverse cross-sectional area of the ligament, said method comprising:

inserting the at least one ligament into the bone tunnel;

attaching the at least one ligament to the bone;
and

inserting [said] a ligament shim into the bone tunnel so as to occupy a portion of the transverse cross-sectional area of said bone tunnel.

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